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APPLICATION NO.		FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/699,076		10/27/2000	Nicos A. Petasis	06666/005002	9032	
26181	7590	09/26/2006		EXAMINER		
FISH & R	ICHARD	SON P.C.	EPPERSON, JON D			
PO BOX 1022 MINNEAPOLIS, MN 55440-1022				ART UNIT	PAPER NUMBER	
				1639		
				DATE MAILED: 09/26/2006		

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
		Application No.				
	Office Assistant Communication	09/699,076	PETASIS ET AL.			
	Office Action Summary	Examiner	Art Unit			
		Jon D. Epperson	1639			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)	Responsive to communication(s) filed on 27 J	<u>une 2006</u> .				
2a)⊠	This action is FINAL. 2b) ☐ This action is non-final.					
3) 🗌	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
 4) Claim(s) 12,19-21 and 34-42 is/are pending in the application. 4a) Of the above claim(s) 19, 20, 34 and 40-42 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 12,21 and 35-39 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 						
Applicati	on Papers					
9)	The specification is objected to by the Examino	er.				
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority u	under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
	at(s) te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail D	ate			
3) Infor	mation Disclosure Statement(s) (PTO/SB/08) or No(s)/Mail Date	5) Notice of Informal F 6) Other:	Patent Application			

DETAILED ACTION

Please note: There is a change in Examiner handling prosecution in this case from Mark Shibuya to Jon Epperson

Status of the Application

- The Response filed June 27, 2006 is acknowledged. 1.
- 2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Status of the Claims

3. Claims 12, 18-21, 29 and 34-44 were pending. Applicants amended claims 12, 19, 20, 21, 35, 36, 37, 38, 39 and canceled claims 18, 29, 43 and 44. No claims were added. Therefore, claims 12, 19-21 and 34-42 are currently pending.

Election/Restriction

- 4. Applicant elected if species without traverse is acknowledged (e.g., see 6/27/06 Response).
- 5. Claims 19 and 20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species (see 6/27/06 Response, "Claims 12, 21, 34-42 read on the elected combinatorial library"). In addition, the Examiner notes that claims 34 and 40-42 remain withdrawn from consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species and/or invention (e.g., see 11/4/05 Response, page 3, paragraph 4).

6. Therefore, claims 12, 21, 35-39 are examined on the merits in this action.

Withdrawn Objections/Rejections

7. The Palfreyman et al. rejection under 35 U.S.C. § 102/103 is withdrawn in view of Applicants' amendments to claim 12 specifying the "form" of the library (e.g., see 3/6/06 response, page 11). The rejection under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicants' amendments to claim 12 and cancellation of claim 44. The Kick et al. rejection under 35 U.S.C. 102/103 is withdrawn in view of Applicants' amendments to claim 12 and arguments on pages 12 and 13. The Gordon et al. rejection under 35 U.S.C. § 102(b)/103(a) is withdrawn in part in view of Applicants' amendments to claim 12 specifying the possible alkyl substitution and arguments on page 15 of the 3/6/06. All other rejections are maintained and the arguments are addressed below.

Outstanding Objections and/or Rejections

35 USC § 102/103

8. Claims 12, 21, 35 and 36 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gordon et al. (Bioorganic & Medicinal Chemistry Letters, 1995, Vol. 5, No. 1, pp. 47-50) (of record).

For *claim 12*, Gordon et al. disclose a library of piperazinedione compounds and/or intermediates for their preparation (e.g., see entire document), which anticipates the claimed invention. For example, Gordon et al. disclose 10 mixtures of 10 substituted

amines (e.g., see scheme 2, compound 7 with R^1 and R^2 groups shown in previous table on page 48), which anticipates the claimed library wherein H^3/H^4 = hydrogen (formed from the R^2 -CHO group that subsequently is reacted with the amine via reductive amination, see Table on page 48), R^5 = n-C₈H₁₇ (i.e., alkyl), cyclohexyl (i.e., cycloalkyl), phenyl (i.e., aryl), etc. as shown for the " R^2 " substituents in the middle column on the bottom table of page 48), R^1 = hydrogen (e.g., the NH shown on compound 7 in scheme 2 on page 49) and R^2 = C-R¹ (e.g., see compound 7 in scheme 2 wherein the R^1 substituents are shown in the table on the bottom of page 48 including hydrogen, methyl, Val and Leu "alkyl" groups, etc.). In addition, the solid support is bound "through" the R^2 group (i.e., the solid support can either be the sphere alone or, alternatively the sphere-O₂C- linkage). Please note that Applicants' "comprising" terminology (e.g., "having") does not preclude the use of additional "linker" groups (e.g., -O₂C-) in addition to the requisite "- R^2 -" linkage. In addition, it is unclear what the phrase "coupled to the substrate through R^1 or R^2 " means (e.g., see 35 U.S.C. 112, second paragraph).

For *claim 21*, Gordon et al. disclose an "array" of compound (e.g., see scheme 1 wherein 10 mixtures are "arrayed" in the split-and-mix process; see also page 48, paragraph 1, "Wang resin by a range of aldehydes, affording an <u>array</u> of novel, resinbound secondary amines including 3).

For *claim 35 and 36*, Gordon et al. disclose at least one of the compounds is present in diasteromeric excess or enantiomeric excess (e.g., see scheme 1, showing excess of "S" configuration e.g., ~100%).

Art Unit: 1639

The product of Gordon et al. meet all of the structural limitations of the claimed product (see above) except for the product-by-process limitations (e.g., made via the use of an organoborane represented by formula 15 of formula 19 as set forth in claim 12) and thus would either anticipate or render obvious the claimed library. See MPEP § 2113, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-byprocess claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)." Here, Applicants' claims are drawn to a library (i.e., a product), but are defined by various method steps that produce said library and, as a result, represent product-by-process claims. Thus, the process limitations do not appear to provide any patentable weight to the claimed invention in accordance with MPEP § 2113. One of ordinary skill would expect the product to be the same no matter how it was synthesized and/or prepared.

Response

9. Applicant's arguments directed to the above 35 U.S.C. § 102 rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

Art Unit: 1639

[1] Applicants argue, "the present combinatorial library requires that when the compounds are in an array having each compound located at a different position at a substrate, at least one of the compounds is coupled to the substrate through R¹ or R². The values claimed for R¹ and R² do not permit a carboxy substituted alkyl which would be needed to form the compounds of the Gordon et al. reference" (e.g., see 6/27/06 Response, page 14).

Page 6

[2] Applicants argue, "the claimed groups for R1 and R2 in formula 1 are not themselves permitted to be substituted with amino, let alone be a group such as -C(=O)CH(R3)NH2 ..." (e.g., see 6/27/06 Response, pages 14 and 15, especially page 15, middle paragraph).

This is not found persuasive for the following reasons:

[1] The Examiner respectfully disagrees. First, Applicants newly added limitation "coupled to the substrate through R¹ or R²" is vague and indefinite (see 35 U.S.C. 112, second paragraph rejection below), which renders Applicants' argument moot. Second, Applicants' use of "comprising" terminology (e.g., a combinatorial library "comprising" ... in line 1 or, alternatively, an array "having" ... in the 7th line from the bottom), which does not preclude the use of "additional" elements like a -O₂C- spacer between the solid support and the R^{1 or 2} groups. See *Lampi Corp. v. American Power Products Inc.*, 228 F.3d 1365, 1376, 56 USPQ2d 1445, 1453 (Fed. Cir. 2000) (The term "having" was interpreted as open terminology, allowing the inclusion of other components in addition to those recited). That is, the claims do not exclude the use of a carboxy substituted alkyl group as purported.

[2] The Examiner finds this argument persuasive in light of the currently amended claims and withdraws (in part) the rejection with respect to claims 37-39.

Accordingly, the 35 U.S.C. 102/103 rejections cited above are hereby maintained.

Art Unit: 1639

New Rejections

Page 7

Objections to the Claims

10. Claim 12 is objected to because of the following informalities:

- A. Claim 12 as currently amended contains two commas after the "carboxy" term in the third line of the R¹ and R² Markush listing. Correction is requested.
- B. Claim 38 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form or rewrite the claim(s) in independent form. Claim 38 depends from claim 12. Claim 12 recites in part: "R⁵ is selected from the group consisting of alkyl, cyclically, aryl, heteroaryl, alchemy, alkynes and allenyl ... each alkyl is optionally substituted with one or more groups selected from the group consisting of C1-C6 alkyl, C3-C6 heterocycle, aryl, halo, hydroxyl, alloy, and sulfonyl" (i.e., only the "alkyl" group is "substituted", not the "alkenyl" group and, regardless of the group, no "amino" substitution is set forth). In contrast, claim 38 sets forth both an "alkenyl" group with an "amino" substitution for the R⁵ position (see also . Therefore, claim 38 does not further limit claim 12.
- C. Claim 39 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form or rewrite the claim(s) in independent form. Claim 39 depends from claim 12. Claim 12 recites in part: "carboxy" (i.e., CO₂H) and "carboxamido" (i.e.,

Application/Control Number: 09/699,076 Page 8

Art Unit: 1639

CONH) groups for R^4 , not the currently claimed aldehyde (i.e., when $R^{4'} = H$), ester (i.e., when $R^{4'} = alkoxy$), etc. Therefore, claim 39 does not further limit claim 12.

Claims Rejections - 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 11. Claims 12, 21, 35-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. This is a new matter rejection.
 - A. Claim 12 was amended in the 3/6/06 response. However, the Examiner cannot find support for the currently claimed coupling (e.g., a covalent "support-[H⁺]-compound of formula I" product, see 35 U.S.C. 112, second paragraph rejection below). In addition, the Examiner cannot find support for the "at least one" of the compounds being coupled to the substrate language either. The specification only provides for "all" of the compounds being coupled to form the solid-phase library when a coupling resin is used. If applicant believes this rejection is in error, applicant must disclose where in the specification support for this amendment can be found in accordance with MPEP 714.02.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1639

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Page 9

12. Claim 12, 21, 35-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. For claim 12, the phrase "an array having each compound located at a different position at a substrate, at least one of the compounds being coupled to the substrate through R¹ or R²" is vague and indefinite. For example, it would be physically impossible to couple a compound to the substrate "through a [hydrogen] R¹ or R²" atom forming presumably a covalent "support-[H⁺]-compound" product (e.g., see claim 12 wherein the first recited Markush listing for $R^{1/2}$ is hydrogen). In addition, it is unclear how many of the other groups listed in the Markush definition for R^{1/2} could likewise be "coupled" to the substrate when they are "monovalent." For example, an "alkyl" group only has one point of attachment (e.g., -Ak) and, as a result, could not function as a "spacer" to link the substrate to the compound. A bivalent "alkylene" would be required (i.e., -Ak-). If "coupling" refers instead to the loss of some unspecified atoms/electrons (e.g., $-CH_3 \rightarrow -CH_2$) before the attachment can take place to achieve this "spacer" functionality then it is unclear what changes need to be made to accommodate such an attachment. For example, the "hydrogen extraction" mention above (e.g., $-CH_3 \rightarrow -$ CH₂•) could not be used to make the claimed array because the reaction (e.g., free radical) would pull hydrogen atoms off all of the alkyl groups on the molecule "indiscriminately", fostering attachment points at almost every conceivable position on

Art Unit: 1639

Page 10

the molecule (e.g., loss of a hydrogen at an alkyl group on R³ would be just as likely as an alkyl group at R¹). Applicants are requested to clarify and/or correct. Therefore, claim 12 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

B. For **claim 12**, the phrase "provided that the compound of formula 13 is a primary or secondary amine" is vague and indefinite in light of the fact that compound 13 as shown (e.g., R_{2/1}-N-H) cannot be anything other than a primary or secondary amine. That is, formula 13 contains an N-H bond, which would preclude any other possibility (i.e., a tertiary amine). Thus, it is not clear how this newly added limitation further limits and/or clarifies the claimed formula? Applicants are requested to clarify. Therefore, claims 12 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Claims Rejections – 35 U.S.C. 102/103

13. Claims 12 and 35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Kobayashi I (e.g., Kobayashi et al., "Parallel Synthesis Using Mannich-type Three Component Reactions and 'Field Synthesis' for the Construction of an Amino Alcohol Library" *Tet. Lett.* 1996, 37(43), 7783-7786) as evidenced by Kobayashi II (e.g., Kobayashi et al., "Polymer-supported Silyl Enol Ethers. Synthesis and Reactions with Imines for the Preparation of an Amino Alcohol Library" *Tet. Lett.* 1996, 37(16), 2809-2812).

For *claim 12*, Kobayashi I (see entire document) disclose an amino alcohol library that anticipates the claimed invention (e.g., see schemes 2 and 3; see also bottom of page 7783). In this scenario, R^1 = hydrogen; R^2 = Ph (i.e., aryl, see bottom of page 7783,

Amine I), $R^3 = Ph \dots C_6H_{11}$ (i.e., aryl, heteroaryl, alkyl, see bottom of page 7783, Aldehydes A-D), $R^4 = hydrogen$, $R^5 = HO-CH_2-CH(R^1)$ - (i.e., alkyl substituted with hydroxyl, aryl, or alkoxide depending on the nature of the R^1 shown on the bottom of page 7783, PSEE 1-4).

For *claim 35*, Kobayashi I do not explicitly state that the library members are made in diastereomeric/enantiomeric excess, but the Examiner contends that this is an inherent property of disclosed library because Kobayashi II explicitly states that "moderate diasteroselectivity" is produced for the exact same reactions (e.g., see Kobayashi II, page 2812, note 8). Furthermore, the Examiner contends that these compounds are produced as "mixtures" of diastereomers.

The product of Kobayashi et al. meet all of the structural limitations of the claimed product (see above) except for the product-by-process limitations (e.g., made via the use of an organoborane represented by formula 15 of formula 19 as set forth in claim 12) and thus would either anticipate or render obvious the claimed library. See MPEP § 2113, ""[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)." Here, Applicants' claims are drawn to a library (i.e., a product), but are defined by various method steps that produce said library and, as a result, represent product-by-process claims. Thus, the

Art Unit: 1639

process limitations do not appear to provide any patentable weight to the claimed invention in accordance with MPEP § 2113. One of ordinary skill would expect the product to be the same no matter how it was synthesized and/or prepared.

Page 12

14. Claims 12, 21, 37 and 39 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Greeb (U.S. Patent No. 4,772,424) (Published September 20, 1988) as evidenced by Schill + Seilacher (Schill + Seilacher "Amino Acid Based Surfactants" accessed from http://www.in-cosmetics.com/ExhibitorLibrary/420/PERLASTAN_N-acyl_sarcosinate_and_glutamate.pdf on 9/13/06, pages i-xii and 1-8) and Anderson et al. (U.S. Patent No. 3,085,067) (Published April 9, 1963). 12, 21, 35-39

For *claims 12, 37 and 39*, Greeb (see entire document) disclose the use of a mixture [i.e., library] of N-acyl sarcosinates surfactants in cleaning compositions (e.g., see abstract; see also column 3, "Sarcosinate Surfactant" section, especially, lines 39-43, "Specific preferred sarcosinates include sodium oleoyl sarcosinate, sodium cocoyl sarcosinate, sodium lauroyl sarcosinate and mixtures thereof [i.e., a library]"; see also claims, especially claim 4). These surfactants fall within the scope of formula 1 when R¹ = methyl (i.e., alkyl); R² = lauroyl, cocoyl fatty acid side chains (i.e., acylalyl), see also U.S. Patent No. 3,085,067 (incorporated into the Geeb patent atcolumn 3, line 43) which discloses various other fatty acids side chains that can be used (e.g., see Anderson et al., column 2, paragraph 2); R⁴ = carboxy (or alternatively, R⁴ is hydroxyl for claim 39); R^{3/5} = hydrogen. Greeb does not explicitly state that the "free base" of the surfactants is being

Art Unit: 1639

used. However, the Examiner contends that this would be an inherent feature of the cleaning compositions set forth by Greeb because Schill + Seilacher explicitly state that the salts of these surfactants exist in equilibrium with the free base at slight acidic pH values (e.g., see Schill + Selacher, page 3, last full paragraph, "Absoption increases [e.g., sodium lauroyl sarcosinate) at slightly acidic pH conditions, where small amounts of free acid exists in equilibrium with its salt"; see also page i), which is exactly the conditions used by Greeb (e.g., see Greeb, column 4, lines 23-24, "The pH of the present composition ... from 4 to about 8 [i.e., 4-7 is slightly acidic]").

Page 13

For claim 21, Greeb et al. disclose the use of said cleaning compositions to be "arrayed" on a person's scalp for cleaning.

The product of Greeb meet all of the structural limitations of the claimed product (see above) except for the product-by-process limitations (e.g., made via the use of an organoborane represented by formula 15 of formula 19 as set forth in claim 12) and thus would either anticipate or render obvious the claimed library. See MPEP § 2113, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-byprocess claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)." Here, Applicants' claims are drawn to a library (i.e., a product), but are defined by various method steps that produce said library and, as a result, represent product-by-process claims. Thus, the

process limitations do not appear to provide any patentable weight to the claimed invention in accordance with MPEP § 2113. One of ordinary skill would expect the product to be the same no matter how it was synthesized and/or prepared.

Conclusion

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D. September 14, 2006

JON EPPERSON, PH.D. PATENT EXAMINER